

JAN 22 1997

APPENDIX VIII

510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMITTED BY: Applied Medical Resources Corporation
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CONTACT PERSON: Howard V. Rowe

DATE OF PREPARATION: November 5, 1996

NAME OF DEVICE: Applied Medical Clip Applier

CLASSIFICATION NAME: Manual Surgical Instrument for General Use, 21
CFR 878.4800 and Implantable Clip, 21 CFR
878.4300

TRADE NAME: Not established to date.

SUMMARY STATEMENT: The Applied Medical Clip Applier is substantially equivalent to the predicate LIGACLIP™ ERCA Clip Applier device manufactured by Ethicon. The Applied Medical Clip Applier is a sterile single use device intended for ligation of tubular structures or vessels in laparoscopic and general surgical procedures. The Applied Medical Clip Applier consists of a molded plastic clip applier handle with an actuating trigger, a 360° adjustable rotational knob on the shaft, an applicator shaft and clip applier jaws which provide secure placement of the clip to the desired vessel. The applier is sold with a pre-loaded cartridge containing 20 implantable clips. The distal tip of the shaft is a clear material which provides a color coded visual indicator for identification of the last four clips. Following release of the last clip, a lockout mechanism is activated which neutralizes the jaw actuating mechanism and prevents unanticipated cutting or pinching from the applier jaws. Functional performance and biocompatibility tests were performed to verify functional and structural integrity and material safety. All testing demonstrated the Applied Medical Clip Applier introduces no new safety and effectiveness issues when used as indicated.